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10/083,338	02/27/2002	Tomohiro Yasuda	HIRA.0027	8246

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EXAMINER

MAHATAN, CHANNING

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 09/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

3/19

## Office Action Summary

**Application No.**

10/083,338

**Applicant(s)**

YASUDA ET AL.

**Examiner**

Channing S Mahatan

**Art Unit**

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☒ Claim(s) 10 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

Art Unit: 1631

## **DETAILED ACTION**

### *APPLICANTS' ARGUMENTS*

Applicants' arguments, filed 18 June 2004, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### *CLAIMS UNDER EXAMINATION*

Claims herein under examination are claims 1-15.

### **Claims Rejected Under 35 U.S.C. § 112 1<sup>st</sup> Paragraph**

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

### *NEW MATTER*

Claims 1-15 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 3, 5, and all claims dependent therefrom are rejected under 35 U.S.C. § 112, first paragraph. The amendment(s) of "comparing a sequence adjacent to said first fixed-length partial sequence of said first nucleic acid base sequence with a sequence adjacent to said second

Art Unit: 1631

fixed-length partial sequence of the second nucleic acid base sequence to be sufficiently similar via a greedy alignment algorithm” is considered new matter. Applicant indicates: 1) “claims 1-12 are being amended, as set forth in the above marked-up presentation of the claim amendments, in order to more particularly define and distinctly claim applicants invention”; and 2) “new claims 13-15 are being added to recited another embodiments described in the specification”. While there does appear to be support for instant claims 14 and 15 on page 34 and 35, respectively, there does not appear to be support for such broadly encompassing limitations (Refer to below 35 U.S.C. § 112 2<sup>nd</sup> Paragraph Rejection) or for the “greedy alignment algorithm” throughout the specification. Therefore, the above amendments are considered NEW MATTER.

*LACK OF ENABLEMENT*

The rejection of claims 1-12 (herein applied to newly added claims 13-15) under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement are maintained for reasons of record. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-15 are rejected under 35 U.S.C. § 112, first paragraph. The claimed invention is directed to “a method for assembling nucleic acid base sequences”. Absent from the instant claims and the disclosure is guidance, direction, or examples for the above determination step via a greedy alignment algorithm. In the absence procedures for performing the above determination step one skilled in the art would not understand how to assess if the second nucleic acid base sequence and the first nucleic acid base sequence can or cannot be assembled, thereby

Art Unit: 1631

performing the further steps (i.e. assembling the first and second nucleic acid base sequence if it is determined that the sequences can be assembled). No procedures for “determining whether the second nucleic acid base sequence searched in said step and the first nucleic acid base sequence can be assembled by comparing a sequence adjacent to said first fixed-length partial sequence of said first nucleic acid base sequence with a sequence adjacent to said second fixed-length partial sequence of the second nucleic acid base sequence to be sufficiently similar via a greedy alignment algorithm” appear to be disclosed. Applicants are directed to Fields, Wilkinson, and Kende v. Conover and Woodward [170 USPQ 276; How-to-Make Requirement section] which states:

"the description must place the invention in the possession of the public as fully as if the art or instrument itself had been practically and publicly employed. In order to accomplish this, it must be so particular and definite that from it alone, without experiment or the exertion of his own inventive skill, any person versed in the art to which it appertains could construct and use it."

Such independent decisions, judgments, tests, and validation are not considered to be routine experimentation and one of skill in the art practicing the invention would be required to use inventive skill to determine whether a second nucleic acid base sequence searched in said step and the first nucleic acid base sequence can be assembled via a greedy alignment algorithm. Thus, the specification fails to provide one of skill in the art proper guidance, direction, or examples to use the claimed invention.

### **Claims Rejected Under 35 U.S.C. § 112 2<sup>nd</sup> Paragraph**

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1631

Claims 1-15 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

*VAGUE AND INDEFINITE*

Claims 1, 3, 5, and all claims dependent therefrom recite the limitation “fixed-length partial sequence” which is considered vague and indefinite. The above limitation implies a range or criteria defining a fixed length partial sequence thereby. For instance, is a “fixed length partial sequence: 1) one nucleotide long; 2) two nucleotides long; etc? Applicants can resolve this issue by particularly pointing out what defines a “fixed-length partial sequence”.

Clarification of the metes and bounds, via clearer claim language, is requested.

Claims 1, 3, 5, and all claims dependent therefrom recite the limitation “sufficiently similar” which is considered vague and indefinite. It is unclear what limitation(s) Applicants' regard “sufficiently similar” to be, wherein such language implies a degree/criteria that is considered to be “sufficiently similar” (i.e. degree of similarity). Applicants can resolve this issue by particularly pointing out what the limitations “sufficiently similar” encompasses.

Clarification of the metes and bounds, via clearer claim language, is requested.

*MISSING ESSENTIAL STEPS*

Claims 1, 3, 5, and all claims dependent therefrom are rejected under 35 U.S.C. § 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See M.P.E.P. § 2172.01. For example, claim 1 recites the limitation determining whether the second nucleic acid base ...to be sufficiently similar via a greedy alignment algorithm” which is unclear. Absent from the instant claims are steps for performing a

Art Unit: 1631

greedy alignment algorithm as required by Applicants' amendment. Clarification of the claim language is requested.

*OBJECTION TO CLAIM*

Claim 10 is objected to because of a grammatical error. It appears the instant claim language "to proceed the searching, comparing, and assembling steps" should be replaced with "to precede the searching, comparing, and assembling steps".

*OBJECTION OF DISCLOSURE*

The disclosure is objected to because of the following informalities:

The specification on page 16 (line 7) contains a spelling error, wherein it appears "peed" should be replaced with "speed". Appropriate correction is requested.

*EXAMINER COMMENT*

With respect to Zhang et al. reference the specification states the following:

"In this sequence comparison, a position of the exact matching whose length is  $s$  between the consensus sequence and the input sequence is apparent, so that a high speed algorithm described in Zhang, Z. et al., J. Comput. Biol., 7 (1-2): 203-14, 2000 is used." (page 16, lines 5-9 of the Specification).

However, no further citation of the reference can be found in the specification. Further, Applicants have asserted in the arguments filed 18 July 2004, that the above reference is 'incorporated by reference', which is incorrect. Zhang et al. is not 'incorporated by reference'.

*ACTION IS FINAL, AS NECESSITATED BY AMENDMENT*

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

Art Unit: 1631

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

**No Claims Are Allowed.**

*EXAMINER INFORMATION*

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Channing S. Mahatan whose telephone number is (571) 272-0717. The Examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (571) 272-0722.



Art Unit: 1631

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Date:

*August 31, 2004*

Examiner Initials:

*CSM**Marianne P. Allen*MARIANNE P. ALLEN  
PRIMARY EXAMINER*9/1/04**AU1631*